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**REPORT OF RISING POWERS POLICY WORKSHOP:
GLOBAL GOVERNANCE OF HUMAN EMBRYONIC STEM CELL RESEARCH AND THERAPY – AN EXAMPLE
FROM INDIA**

Held on 15 Mar 2013 at King's College London

This report has been compiled by Alex Faulkner and Saheli Datta
and approved by the workshop participants

A policy workshop was held on 15 March 2013 at King's College London as part of the ESRC funded research 'State strategies of governance in biomedical innovation: the impact of China and India'. This project explores emerging innovation dynamics and trans-national governance in the context of the increasing importance of the life sciences and technologies in countries' and regions' competitive and collaborative economic strategies, and the recognition that biomedical sciences raise difficult questions of ethics and of social impact. The project involves a series of workshops, whose results are designed to inform public policy-making in a range of fields in regenerative and personalised medicine in the UK and the 'Rising Powers' of India and China.

The objective of the workshop was to better understand the regulatory, medical, commercial and legal community's perception of innovative biomedical practices in the emerging nations, and to identify the most relevant debates in the field of human embryonic stem cell (hESC) therapy in the context of a dynamic global marketplace, uncertain science and variable regulation globally. The workshop was chaired by the research Principal Investigator Brian Salter, Professor of Politics in the Department of Political Economy, KCL, supported by Co-Investigators Dr Alex Faulkner (University of Sussex) and Dr Stuart Hogarth (KCL). The workshop generated wide interest and was attended by 20 delegates ranging from clinicians, academics, researchers, lawyers and regulators to the social sciences including sociology and anthropology. Professor Pranav Desai, chairperson of the Centre for Studies of Science Policy (CSSP) of the Jawaharlal Nehru University (JNU) in Delhi, India, a collaborating partner in the research, provided an introduction on the Indian context of biotech biomedical innovation in general and stem cell innovation in particular.

Dr Geeta Shroff, a professional gynaecologist and embryologist, and founder and practitioner of embryonic stem cell therapy clinics in Delhi, India, presented her work in India. Dr Shroff is known widely as a controversial practitioner, involved in providing treatment to numbers of 'stem cell tourists' with unmet medical needs from both India and elsewhere in the world. This report concentrates on the discussion prompted by Dr Shroff's presentation.

The discussions centred on the global market, the scientific community, the national Indian context, and ethical and regulatory dimensions of stem cell research and therapy. Based on these central issues, this report presents first the ethical perceptions of UK-based participants and Dr Shroff's position, and then summarises discussion about difference and commonalities of formal regulation, and issues of what sort of innovation model is represented by Dr Shroff's work to date, in the context of issues of its visibility in scientific and wider public communities. Finally we conclude that the workshop helped identify the current central areas of resistance to human embryonic stem cell therapies in 'western'-centric scientific and policy perception, while emphasizing some of the local and national Indian positions and responses to these perceptions. The workshop helps provide pointers for future research and policy development to understand the 'global biopolitics' and policy implications of this innovative field.

Ethical Perceptions

The workshop discussions centred on some key concerns in stem cell therapy as practised in the transitioning economies:

Donor consent for stem cell therapy in India – the attendees expressed concern for the nature and scope of consent of the in-vitro embryo donor from whom Dr Shroff's embryonic stem cell lines are generated. For instance one question was to what extent consent was sought and received from the donor of the embryo from which Dr Shroff's stem cell lines were generated. Dr Shroff's response that she had sought consent from the donor 11 years ago and had since maintained 'long term' documentary evidence of this consent' thus fulfilling the basic criteria as set by the Government of India for developing cell lines, was perceived as too simplistic and tinged with perceptions of local medical standards as 'uncaring' of donors or their consent. This view can be seen as reflecting broader public criticisms of the ethics of using readily available human subjects for clinical experimentation in the developing world. However, this negative perception vied with a pervading sense of the diffuse and unexplored ethical boundaries accompanying novel medical practices like stem cell therapy: "indeed it was impossible to have sought full consent at the time," emphasizing the regional differences in attitudes to informed consent and its evolving nature. Dr Shroff obtained consent in the year 2000 when it was impossible for the donors, doctors or the regulatory authorities to foresee the possible global use of the stem cell lines. A noteworthy basis of divergent regional ethical perceptions was perceived as rooted in the divergent regional religious beliefs with Catholic values surrounding abortions (and terminated embryos) in the Christian world being juxtaposed to Hindu beliefs in chimeras and embryos as fountainheads of civilizations.

Human trials of embryonic stem cell therapy are still rare. Nevertheless, alleged lack of clinical trials for hESC in India revealed American-European scientific concerns about liberal standards of ensuring patient health and safety in regulatory contexts such as India's. For instance, questions like 'how safe is it to use stem cell therapy without a set number of clinical trials?' or questions of dosage i.e. 'how to determine optimum level of cell growth without trials?' etc., revealed strong beliefs that patient health and safety was seen as not a sufficient priority in India. In response, Dr Shroff while agreeing to the necessity of clinical trials, emphasised the crucial need for alternative policies to the current norm of clinical trials in emerging fields such as stem cell therapy, which did not fit the standard model of medical treatment. For Dr Shroff, the question of RCTs before treating patients, a majority of whom are medically deemed as 'terminal' or 'incurable,' is a "non-sequitur" not only in terms of patient health but also ethically in terms of a doctor's responsibility to use whatever means possible to cure her patients. In this regard, Dr Shroff's position that "we do not harm our patients" when asked if her attitude to clinical trials was "typical of the Indian medical profession", was countered by Dr Shroff's view that such an attitude would be shared by *any* medical practitioner. So Dr Shroff's response revealed a higher ethical priority accorded to "saving lives" *now*, rather than spending precious time running clinical trials. These positions were not clearcut, however, one scientist commenting that "western snobbery about clinical trials...that mapping the brain of a fruit fly is necessary before treating a Parkinson's patient," speaks of some divisions amongst the western scientific medical community about the appropriateness and proper extent of clinical trials, and the possibility of creating different trial and evidence rules for promising emerging therapies.

Market, Scientific Community, and Regulatory Aspects

A set of contentious issues emerged around what might be termed some 'closed' or relatively invisible aspects of Dr Shroff's practice in particular and more generally of the context of the prevailing standards

and regulation in India, when judged by those of broadly shared scientific conventions of the US, Western Europe and elsewhere. The central issues in these respects perceived to be of concern by many of the workshop attendees were:

Perceived liberal regulatory oversight– revealed concerns about the lack of stringent policies for monitoring patient health and safety primarily grounded on perceptions of comparatively lenient policies being used as a tool for growing the medical enterprises of the developing world (through medical tourism, patenting and so on). A view to be found in some mass media commentary on clinics advertising on the internet globally and expressed somewhat in the workshop, was one that many centres offering stem cell therapy are motivated by aims that are overwhelmingly economic, novel medical practices being seen as little more than business ventures and not centres of altruistic patient care. However, Dr Shroff stated that her service is not advertised (though it does have an online presence). A social science academic suggested that Dr Shroff's practice, in terms of types of biomedical innovation, was not in fact a commercial product-based model. Raised by the subject of Dr Shroff's application for worldwide patents (with both United States and European Patent offices) of her stem cell "product", a critical economic perspective suggested an apparent "appetite for commercialization both within India and outside" in stem cell therapy, and a regulatory view was that the "broader point is recognizing the policy approach- that the patent is not as crucial as regulatory protection" - such as might be granted through the type of market exclusivity that a regulator such as the European Medicines Agency might provide. In this connection it was 'hard to envisage' a *generic* hESC product (that is, such as Dr Shroff's) receiving such market protection.

Further, there was detailed discussion prompted by Dr Shroff's presentation, about the type of regulatory regime, the safety of hESC procedures and the evidence for safety in the context of regulatory control. The unclear status of hESC therapy in Indian regulation was pointed out, with speculation as to whether for example it should be subject to drug price controls or not – hESC could also be treated as transplantation, involving a different set of regulations. Dr Shroff explained how her stem cell lines and her clinical practice met Indian and international standards, referring to the technical standards of Good Manufacturing Practice, Good Clinical Practice and Good Laboratory Practice, and her practice having government approval. She also presented imaging data on several individual patients (see slides). However, these were felt to fall short of a full 'safety profile' and methodological rigour that would be expected to include timeframes, endpoints and other criteria. For instance, there was expressed concern about the reliability of the scientific technique used for reaching a desired 'optimum' number of cell growth in patients without the data from an acceptable number of randomised clinical trials (RCTs). A regulator commented : "The use of medicinal products derived from human embryonic stem cells requires adequate testing of the cells at various stages of the manufacturing process with regard to determining the safety of the product. This is true of all medicinal products but is especially important in products of this type (derived from human embryonic stem cells) because of the risk of safety concerns developing at a late stage after administration." Dr Shroff expressed herself as 'passionate about rigour' and safety being a major concern in every step of the development of her techniques, which had passed government scrutiny. In relation to matters such as cell viability, chromosomal stability, infection-checking and cell robustness, Dr Shroff had collected data, and pointed out also that her cell lines were cultured (unusually) without any animal products. However, there apparently remained amongst workshop participants some lack of clarity about the extent to which Dr Shroff's work had produced such data, and this was linked partly to the issue of publication and peer review – see below.

In line with scientific research standards, the attendees were generally agreed in considering peer-reviewed publications, public availability of clinical and patient data, and documentation of regulatory approvals in the public domain as key steps in proving competence of any scientific endeavour. Dr Shroff's apparent reticence and low profile to date in these matters arguably have not only shrouded her work in mystery but have also encouraged perceptions of her work as ill-regulated and commercially driven.

It was generally perceived that publishing work substantiated with empirical evidence would earn Dr Shroff's practice needed credibility and 'respect.' Dr Shroff pointed out that she had publications in the planning stage but was waiting until her patent applications were decided before exposing her data more widely to scientific and public scrutiny. She pointed out that the data in her patent applications are publicly available.¹ It was also notable that Dr Shroff expressed an 'open doors' policy for interested parties to visit her laboratories and clinics to 'see for themselves', and referred to a Clinical Research Organisation (CRO) and clinicians who had visited the centre and given 'positive reports'. Questioned about the actual sharing of cells with other scientists and practitioners in India, Dr Shroff was open to this, though has not made this step yet pending the patent application decision. There was some agreement that the type of evidence required for hESC was not the same as for conventional pharmaceutical clinical trials, but the need for 'public evidence' remained. Dr Shroff noted that her attempts some years ago to speak at meetings of the International Society of Stem Cell Research (ISSCR), a leading international scientific standards organisation, had not resulted in the offer of an opportunity to do so. This resulted in a suggestion that the ISSCR as an organisation had possibly become somewhat more representative of the stem cell science emerging from Rising Powers countries more recently. However, there remained a doubt expressed that Dr Shroff's evidence base would meet the expectations of transnational organisations such as the ISSCR, which has a clear worry about the ethics of profiting from 'vulnerable patients', and is currently dominated by members from the most powerful nationals in the life sciences including USA, UK, other EU countries and other powerful OECD nations.

In summary, the workshop helped identify some of the general, central areas of the developed economies and health systems' resistance to human embryonic stem cell therapies allowed under a permissive regulatory system such as India's, while emphasizing some of the alternative responses to these perceptions, and providing insight into key features of India's alternative regulatory and political culture. The debates and outcomes of the workshop are expected to provide useful pointers for future research and policy development to understand the 'global biopolitics' of this innovative, developing field.

¹<http://patentscope.wipo.int/search/en/detail.jsf?docId=WO2007141657&recNum=21&maxRec=21&office=&prevFilter=&sortOption=Pub+Date+Desc&queryString=FP%3A%28geeta+shroff%29&tab=PCTDescription>